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ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: METHODS AND COMPOSITION FOR SOFT TISSUE FEATURE RECONSTRUCTION

(57) Abstract: This present invention describes methods and compositions useful for the reconstruction of various soft tissue fea-  
tures such as lips, areola, and many other features by taking a mold of the skin feature to be replaced, such as the areola, prior to  
surgical resection, re-creating the size and shape of the soft tissue feature, for example, the nipple and areola, and making a poly-  
mer or biopolymer scaffold that is biocompatible, has the ability to allow the epithelization of the skin cells over the polymer, the  
capability of cell integration into the body of the scaffold, as well as the capability of infiltration of surrounding nerve fibers into the  
substance of the scaffold, so that the patient may have the benefit of a reconstructed soft tissues feature that not only has the same  
size and shape and appearance as the native tissue, but also has functional sensation.



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# INTERNATIONAL SEARCH REPORT

International Application No  
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**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61L27/38 A61L27/44 C12N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61L C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/25396 A (THE REGENTS OF THE UNIVERSITY OF MICHIGAN; UNIVERSITY OF MASSACHUSETTS) 27 May 1999 (1999-05-27) page 2, line 11 - line 23 page 9, line 1 - page 10, line 23 page 12, line 23 - page 13, line 11 page 15, line 21 - page 16, line 12 claims 1,7,8,15,17	1-12
X	WO 99/52356 A (CHARLOTTE-MECKLENBERG HOSPITAL AUTHORITY; HALBERSTADT, CRAIG, R; HOLDE) 21 October 1999 (1999-10-21) page 3, line 7 - line 18 page 9, line 8 - line 28 page 11, line 7 - line 28 page 12, line 11 - line 20 page 12, line 27 - page 13, line 19 page 15, line 11 - line 28	1-12
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
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- \*Z\* document member of the same patent family

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Name and mailing address of the ISA

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 716 404 A (VACANTI ET AL) 10 February 1998 (1998-02-10) column 6, line 48 - column 8, line 31 column 9, line 60 - column 10, line 16 column 10, line 48 - column 11, line 7; claims 1-11</p> <p>-----</p>	1-12
A	<p>US 5 041 138 A (VACANTI ET AL) 20 August 1991 (1991-08-20) claims 1-22; figures 1a,1b</p> <p>-----</p>	1-12
A	<p>LU ET AL.: "Diamond-like carbon as biological compatible material for cell culture and medical application" BIO-MEDICAL MATERIALS AND ENGINEERING, vol. 3, no. 4, 1993, pages 223-228, XP008048975 USA page 224 page 228</p> <p>-----</p>	1

## INTERNATIONAL SEARCH REPORT

International application No.  
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### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
Although claims 5-12 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9925396	A	27-05-1999	AU 1588099 A WO 9925396 A2	07-06-1999 27-05-1999
WO 9952356	A	21-10-1999	AU 3552099 A CA 2330104 A1 EP 1069822 A1 JP 2002511284 T WO 9952356 A1	01-11-1999 21-10-1999 24-01-2001 16-04-2002 21-10-1999
US 5716404	A	10-02-1998	AT 290892 T AU 717861 B2 AU 4521796 A CA 2207757 A1 DE 69534083 D1 EP 0797460 A1 JP 10510736 T WO 9618424 A1	15-04-2005 06-04-2000 03-07-1996 20-06-1996 21-04-2005 01-10-1997 20-10-1998 20-06-1996
US 5041138	A	20-08-1991	AT 142511 T AU 635025 B2 AU 5556890 A CA 2051663 A1 DE 69028524 D1 DE 69028524 T2 DK 469070 T3 EP 0469070 A1 ES 2095252 T3 JP 6006155 B JP 4505717 T WO 9012603 A1 US 5736372 A US 5567612 A US 5804178 A US 5759830 A US 6309635 B1 US 2002115165 A1 AT 139432 T CA 1340581 C DE 3751843 D1 DE 3751843 T2 EP 0299010 A1 JP 7102130 B JP 1501362 T WO 8803785 A1 US 5770193 A US 5770417 A	15-09-1996 11-03-1993 16-11-1990 18-10-1990 17-10-1996 13-02-1997 30-09-1996 05-02-1992 16-02-1997 26-01-1994 08-10-1992 01-11-1990 07-04-1998 22-10-1996 08-09-1998 02-06-1998 30-10-2001 22-08-2002 15-07-1996 08-06-1999 25-07-1996 12-12-1996 18-01-1989 08-11-1995 18-05-1989 02-06-1988 23-06-1998 23-06-1998